K080422

510(k) Summary
as required by 807.92

MAR 10 2008

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission

February 14, 2008

4. Device Trade name
5 Megapixel Monochrome LCD Monitor, RadiForce GS520

5. Common/Usual Name:

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number:

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	5 Megapixel Monochrome LCD Monitor
Model Name	:	RadiForce GS510
510(k) No.	:	K062054

8. Description of Device

RadiForce GS520 device is a digital image display. G520 displays high-definition (5 Megapixel) medical imaging.

9. Intended Use

RadiForce GS520 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with the performance specified by the manufacturer of the system.

10. Substantial Equivalence to Predicate Device

RadiForce GS520 is substantially equivalent to GS510. GS520 employs the maximum resolution values same as that of GS510. GS520 changed the Power Supply. We performed the Electrical Safety and the Electrical Compatibility (EMC) Testing. The certification of UL 60601-1:2003 and EMC Test report were included in this 510(k) submission. The software is modified. Revised the Software Information is included.
Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Hiroaki Hashimoto
Manager
Eizo Nanao Corporation
Engineering Management Section
153 Shimokashiwano-cho
Hakusan, Ishikawa-ken
JAPAN 924-8566

MAR 10 2008

Re: K080422
Trade/Device Name: 5 Megapixel Monochrome LCD Monitor (RadiForce GS520)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2008
Received: February 15, 2008

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not known~~ K080422

Device Name : 5 Megapixel Monochrome LCD Monitor, RadiForce GS520

Indications for Use:

RadiForce GS520 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with performance specified by the manufacture of the system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080422